

18. (New) The system of claim 12, wherein the predetermined expiration date corresponds to said housing.

19. (New) The system of claim 12, wherein the predetermined expiration date corresponds to a set of two or more test strips.

REMARKS

Claims 8-13 were pending at the time of the instant Office Action. Claims 8 and 10 were rejected under 35 U.S.C. § 103(a) as obvious over European patent 0 573 598 to Grant et al. ("Grant" herein). Claims 9 and 11 were rejected under 35 U.S.C. § 103(a) as obvious over the combination of Grant and U.S. Patent No. 4,833,088 to DeSimone et al. ("DeSimone" herein). Claims 12 and 13 were rejected under 35 U.S.C. § 103(a) as obvious over the combination of Grant and U.S. Patent No. 5,989,917 to McAleer et al. ("McAleer" herein). Claims 8, 10, and 12 were also rejected under the judicially created doctrine of obviousness-type double patenting. Applicants respond to each rejection as discussed herein.

Among other things, claim 8 recites "an optics system for alignment with [a] removable test strip, the optics system comprising a lens, an emitter and a detector, wherein the emitter and the detector are mounted in the electronics printed circuitboard relative to the alignment fixturing [and] an optics block holder mounted in the electronics printed circuitboard in alignment with the alignment fixturing, the optics block holder aligning the test strip to the test pad and positioning the optics system to focus light from the light emitter and to the detector;" While the Office Action asserts that the emitter, detector, and block holder per this claim are present in Grant, it acknowledges that "Grant differs from the claimed invention in that a lens is not provided in the optical system," asserting based on official notice that "the use of a lens [is] obvious to one

having ordinary skill in the art at the time of [the] invention as a means to properly focus the light onto the sample and detector.”

Applicants respectfully submit that the use of a lens in the system as claimed provides substantial and unexpected advantages over the system as described in Grant. For example, use of a lens in an optic system wherein the emitter and detector are mounted in a printed circuit board, in conjunction with a processor that controls the assay system in accordance with calibration information uniquely specific to a reagent associated with a set of test strips, allows accurate processing of a much smaller sample, less test strip carrier, and lower-cost components than could otherwise be used (see the Summary of the Invention in this application). The solution disclosed and claimed in the present application provides an unexpected advantage over the prior art, and Grant neither shows nor suggests the combination. Analogous arguments apply to claim 10, and the rejection of these claims (8 and 10) should be withdrawn.

In addition, claim 10 recites “a processor ... controlling the assay system such that a predetermined number of test strips are assayed based on signals from the light detector, wherein the predetermined number corresponds to the number of test strips of a set of one or more test strips.” The Office Action asserts that such a processor is disclosed at Grant, col. 17, ll. 1-18, which read:

... old ROM key 64 from the instrument 10 and discards it. A new ROM key 64 is packaged in every supply of strips 106. The user inserts the new ROM key 64 containing information pertinent to the new supply of strips 106 into the key housing portion 18 on the instrument 10 prior to turning the instrument 10 on. When the instrument 10 is turned on, the instrument 10 checks the integrity of the data contained in ROM key 64 via a checksum method. If the ROM key 64 is found to be questionable, then a code error is displayed 424. During the performance 410 of a test, prior to the calculation 412 of a new glucose result, the instrument 10 checks the ROM key 64 to see if it has been changed. If the ROM key 64 has been changed since the instrument 10 was turned on, a code error is displayed 424. The instrument 10 remains in this display until it either times itself off (5 minutes) or is turned off.

This passage merely suggests that a user of the Grant system is likely only to use a ROM key as many times as there are strips in the accompanying supply. Grant discusses checking the integrity of the data in the ROM key, protecting against a key change during testing, and obtaining maximum and minimum acceptable test results for a particular set of strips, but neither shows nor suggests a processor limiting the system to "a predetermined number of test strips" as recited in claim 10. Because the reference neither shows nor suggests this claim limitation, the rejection over Grant should be withdrawn.

Because they depend from parent claims 8 and 10, respectively, analogous arguments apply to claims 9 and 11, which were rejected over the combination of Grant and DeSimone. Claim 9 recites "a removable calibration chip, the calibration information [uniquely specific to a reagent associated with a set of one or more test strips, per parent claim 8] being provided by the removable calibration chip." Claim 11 recites "a removable calibration chip, the predetermined number [corresponding to the number of test strips of a set of one or more test strips per parents claim 10] being provided by the removable calibration chip." Neither Grant nor DeSimone suggest such calibration chips.

In particular, DeSimone's calibration chip does not provide "calibration information uniquely specific to a reagent associated with a set of one or more test strips" (per claim 9), instead receiving light signals in the absence of the reagent strips:

Light emitted by the light source strikes a calibration chip in the instrument providing a first signal used to calibrate the photometer. The calibration step is followed by the light source again emitting light that strikes the reagent area on the reagent strip. Light is reflected into the instrument and is converted to a second electrical signal. A microcomputer computes the first signal to calibrate the instrument and converts the second signal into a direct blood glucose value. (DeSimone, col. 1, line 62 to col. 2, line 2.)

Likewise, there is no suggestion in the cited references that a removable calibration chip can "provide a predetermined number" (as recited in claim 11 in relation to parent claim 10).

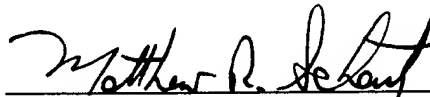
Because the cited references neither show nor suggest a calibration chip per claim 9 or claim 11, the rejection of those claims should be withdrawn.

Claim 12 recites an optics system similar to that of claim 8, and the arguments presented above in favor of the validity of claim 8 apply here as well. The combination with McAleer does nothing to overcome this weakness, and the rejection of claim 12 and its dependent claim 13 should be withdrawn.

As noted above, claims 8, 10, and 12 were rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,285,484. Applicants have enclosed a terminal disclaimer as to this application in relation to the '454 patent, obviating that rejection.

In light of the above amendments and remarks, it is believed that all pending claims are in condition for allowance, and prompt action to that end is respectfully solicited. Applicants reserve their existing rights to provide evidence of invention prior to the effective date of one or more references discussed herein and/or to pursue other claims to related subject matter in one or more continuation applications, and ask that the Examiner call the undersigned if any issues remain that might be resolved by telephonic interview.

Respectfully submitted,



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ADDITIONAL VERSION TO SHOW CHANGES MADE

Claims 8, 10, and 12 were amended as follows:

8. (Amended) A multi-use assay system for use with a removable test strip having a test pad, the multi-use assay system comprising:

an electronics printed circuit board having an alignment fixturing;

an optics system for alignment with the removable test strip, the optics system comprising a lens, an emitter and a detector, wherein the emitter and detector are mounted in the electronics printed circuit board relative to the alignment fixturing;

a housing for containing the optics system and holding the removable test strip in position relative to the optics system;

an optics block holder mounted in the electronics printed circuit board in alignment with the alignment fixturing, the optics block holder aligning the test strip to the test pad and positioning the optics system to focus light from the [light] emitter and to the detector; and

a processor in communication with the detector, the processor controlling the assay system in accordance with calibration information uniquely specific to a reagent associated with a set of one or more test strips.

10. (Amended) A multi-use assay system for use with a removable test strip having a test pad, the multi-use assay system comprising:

an electronics printed circuit board having an alignment fixturing;

an optics system for alignment with the removable test strip, the optics system comprising a lens, an emitter and a detector, wherein the emitter and detector are mounted in the electronics printed circuit board relative to the alignment fixturing;

a housing for containing the optics system and holding the removable test strip in position relative to the optics system;

an optics block holder mounted in the electronics printed circuit board in alignment with the alignment fixturing, the optics block holder aligning the test strip to the test pad and positioning the optics system to focus light from the [light] emitter and to the detector; and

a processor in communication with the [light] detector, the processor controlling the assay system such that a predetermined number of test strips are assayed based on signals from the [light] detector, wherein the predetermined number corresponds to the number of tests strips of a set of one or more test strips.

12. (Amended) A multi-use assay system for use with a removable test strip having a test pad, the multi-use assay system comprising:

an electronics printed circuit board having an alignment fixturing;

an optics system for alignment with the removable test strip, the optics system comprising a lens, an emitter and a detector, wherein the emitter and detector are mounted in the electronics printed circuit board relative to the alignment fixturing;

a housing for containing the optics system and holding the removable test strip in position relative to the optics system;

an optics block holder mounted in the electronics printed circuit board in alignment with the alignment fixturing, the optics block holder aligning the test strip to the test pad and positioning the optics system to focus light from the [light] emitter and to the detector; and

a processor in communication with the [light] detector, the processor controlling the assay system such that test strips are assayed up to a predetermined expiration date.

The following claims 14-19 were added:

14. (New) The system of claim 8, wherein the set of one or more test strips comprises at least two test strips.

15. (New) The system of claim 9, wherein the set of one or more test strips comprises at least two test strips.

16. (New) The system of claim 10, wherein the predetermined number is at least two.

17. (New) The system of claim 11, wherein the predetermined number is at least two.

18. (New) The system of claim 12, wherein the predetermined expiration date corresponds to said housing.

19. (New) The system of claim 12, wherein the predetermined expiration date corresponds to a set of two or more test strips.